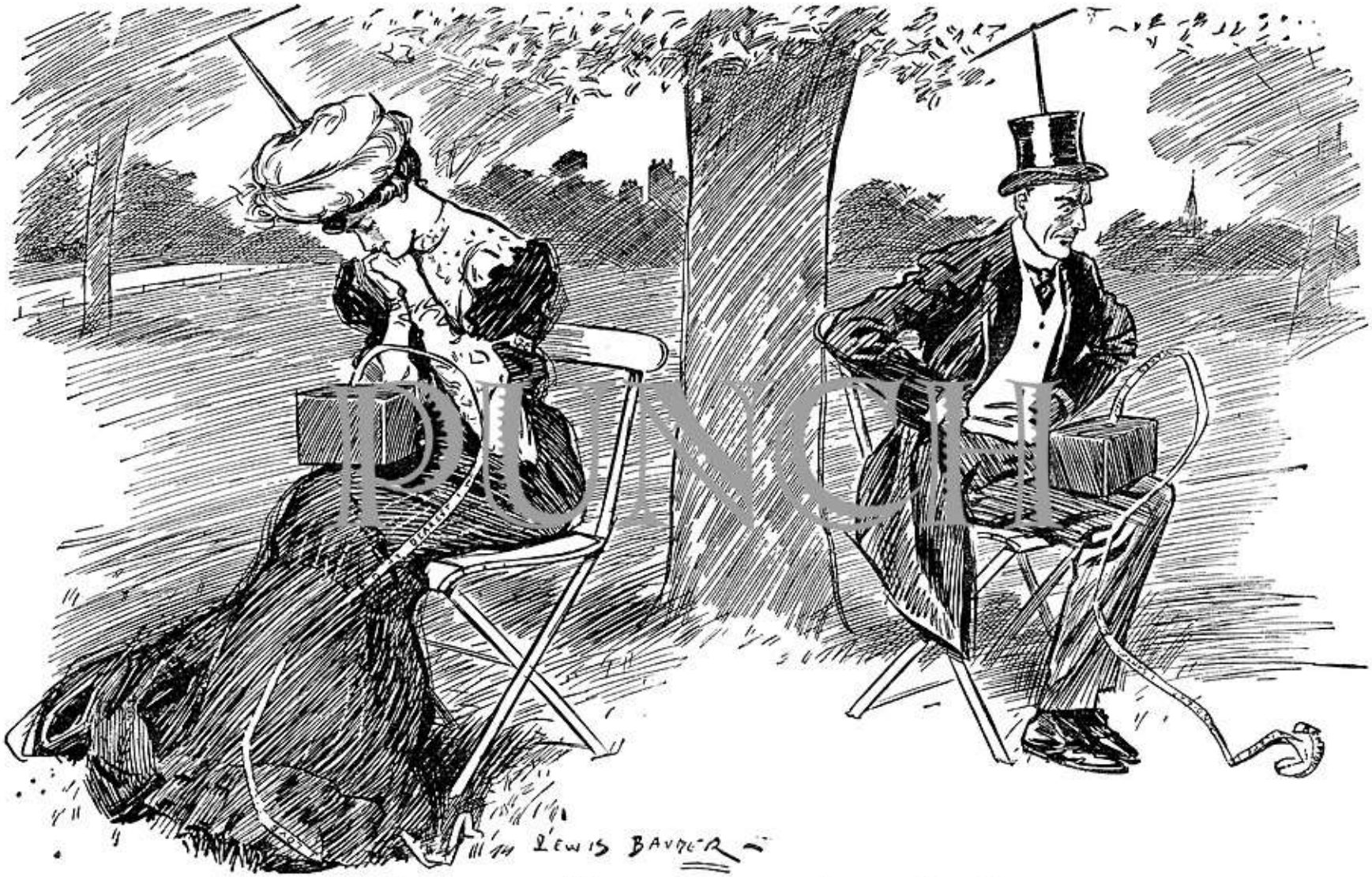
FORECASTS FOR 1907.



IV.—Development of Wireless Telegraphy. Scene in Hyde Park.

[These two figures are not communicating with one another. The lady is receiving an amatory message, and the gentleman some racing results.]

What are the barriers that EQA providers face?

- Based on planning for the 2023 JCTLM Workshop
- These are our challenges

- Our future lies in facing these challenges

- Our success lies in overcoming them!

RCPAQAP
The Royal College of Pathologists of Australasia
Quality Assurance Programs

What are the challenges EQA providers face?

1. Material
2. Regulatory EQA schemes
3. Newer Areas of EQA
4. Sharing and Aggregating data
5. Education

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5. Education

Clinical Chemistry 57:12
1670–1680 (2011)

Reviews

Proficiency Testing/External Quality Assessment: Current Challenges and Future Directions

W. Greg Miller,[1*] Graham R.D. Jones,[2] Gary L. Horowitz,[3] and Cas Weykamp[4]

BACKGROUND: Proficiency testing (PT), or external quality assessment (EQA), is intended to verify on a recurring basis that laboratory results conform to expectations for the quality required for patient care.

or harmonization among different measurement procedures.

Table 3. Evaluation capabilities of PT/EQA related to scheme design.

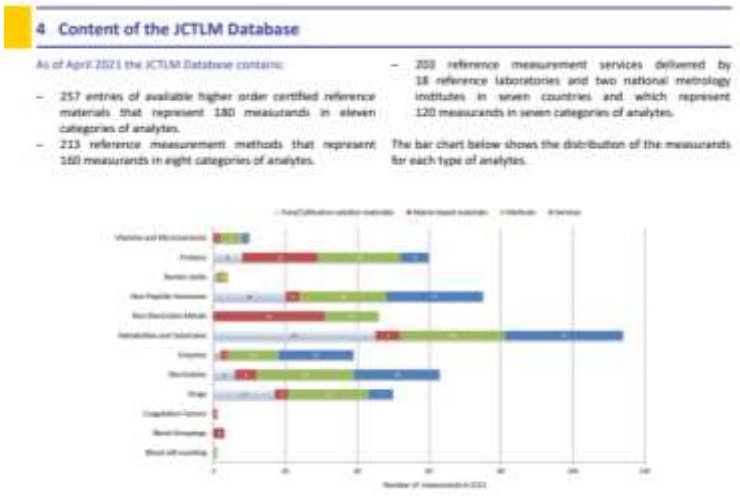
				Evaluation capability						
				Accuracy						
				Individual laboratory					Standardization or harmonization[b]	
	Sample characteristics				Relative to participant results		Reproducibility		Measurement procedure calibration traceability	
Category	Commutable	Value assigned with RMP[a] or CRM	Replicate samples in survey	Absolute vs RMP or CRM	Overall	Peer group	Individual laboratory intralab CV	Measurement procedure interlab CV	Absolute vs RMP or CRM	Relative to participant results
1	Yes	Yes	Yes	X	X	X	X	X	X	X
2	Yes	Yes	No	X	X	X		X	X	X
3	Yes	No	Yes		X	X	X	X		X
4	Yes	No	No		X	X		X		X
5	No	No	Yes			X	X	X		
6	No	No	No			X		X		

[a] RMP, reference measurement procedure; CRM, certified reference material.

[b] Standardization when patient results are equivalent between measurement procedures and calibration is traceable to SI by use of a reference measurement procedure; harmonization when patient results are equivalent between measurement procedures and calibration is not traceable to a reference measurement procedure.

Requirements for EQA

- Commutable
- Replicates
- Value Assignment by Reference Methods -traceability
  - Availability of RM and CRM
  - Cost



Clinical Chemistry 64:3
465–474 (2018)

Special Reports

IFCC Working Group Recommendations for Assessing Commutability Part 3: Using the Calibration Effectiveness of a Reference Material

Jeffrey R. Budd,[1] Cas Weykamp,[2] Robert Rej,[3] Finlay MacKenzie,[4] Ferruccio Ceriotti,[5] Neil Greenberg,[6] Johanna E. Camara,[7] Heinz Schimmel,[8] Hubert W. Vesper,[9] Thomas Keller,[10] Vincent Delatour,[11] Mauro Panteghini,[12] Chris Burns,[13] and W. Greg Miller,[14*] for the IFCC Working Group on Commutability

Clinical Chemistry 59:9
1291–1293 (2013)

Editorials

Commutability Still Matters

W. Greg Miller[1*] and Gary L. Myers[2]

Clinical Chemistry 66:6
749–750 (2020)

Editorial

Further Recommendations on Commutability Assessment

Lindsey G. Mackay*

Clinical Chemistry 64:3
455–464 (2018)

Special Reports

IFCC Working Group Recommendations for Assessing Commutability Part 2: Using the Difference in Bias between a Reference Material and Clinical Samples

Göran Nilsson,[1] Jeffrey R. Budd,[2] Neil Greenberg,[3] Vincent Delatour,[4] Robert Rej,[5] Mauro Panteghini,[6] Ferruccio Ceriotti,[7] Heinz Schimmel,[8] Cas Weykamp,[9] Thomas Keller,[10] Johanna E. Camara,[11] Chris Burns,[12] Hubert W. Vesper,[13] Finlay MacKenzie,[14] and W. Greg Miller,[15*] for the IFCC Working Group on Commutability

Clinical Chemistry 64:3
447–454 (2018)

Special Reports

IFCC Working Group Recommendations for Assessing Commutability Part 1: General Experimental Design

W. Greg Miller,[1*] Heinz Schimmel,[2] Robert Rej,[3] Neil Greenberg,[4] Ferruccio Ceriotti,[5] Chris Burns,[6] Jeffrey R. Budd,[7] Cas Weykamp,[8] Vincent Delatour,[9] Göran Nilsson,[10] Finlay MacKenzie,[11] Mauro Panteghini,[12] Thomas Keller,[13] Johanna E. Camara,[14] Ingrid Zegers,[2] and Hubert W. Vesper,[15] for the IFCC Working Group on Commutability

Clinical Chemistry 66:6
769–778 (2020)

Special Report

IFCC Working Group Recommendations for Correction of Bias Caused by Noncommutability of a Certified Reference Material Used in the Calibration Hierarchy of an End-User Measurement Procedure

W. Greg Miller,[1*] Jeffrey Budd,[2] Neil Greenberg,[3] Cas Weykamp,[4] Harald Althaus,[5] Heinz Schimmel,[6] Mauro Panteghini,[7] Vincent Delatour,[8] Ferruccio Ceriotti,[9] Thomas Keller,[10] Douglas Hawkins,[11] Chris Burns,[12] Robert Rej,[13] Johanna E. Camara,[14] Finlay MacKenzie,[15] Eline van der Hagen,[16] Hubert Vesper,[17] for the IFCC Working Group on Commutability

Clinical Chemistry 66:2
290–293 (2020)

Letters to the Editor

Beware of Noncommutability of External Quality Assessment Materials for Hemoglobin A_{1c}

fresh whole blood or lyophilized hemolysate samples. A +0.2 mmol/mol bias over 1517 laboratories using fresh whole blood material and a −0.5 mmol/mol bias across 649 laboratories using the lyophilized version of the same pool were used to assess commutability of 25 processed quality-control materials for 17 of the most frequently used HbA_{1c} assays, including immunoassays, enzymatic assays, ion-exchange HPLC, boronate affinity HPLC, and capillary electrophore-

Clinical Chemistry 64:3
421–423 (2018)

Editorials

The Enduring Importance and Challenge of Commutability

Ian S. Young*

Commutable material

- Volume needed
- Stability
- Transportability
- Value assignment
- Proving it is commutable

A middle ground?

Clinical Chemistry 59:2
363–371 (2013)

External Quality Assessment of Point-of-Care Methods: Model For Combined Assessment of Method Bias and Single-Participant Performance by the Use of Native Patient Samples and Noncommutable Control Materials

Anne Stavelin,[1,2] Per Hyltoft Petersen,[1] Una Ø. Sølvik,[2] and Sverre Sandberg[2,3]

Clinica Chimica Acta 432 (2014) 77–81

Contents lists available at ScienceDirect

Clinica Chimica Acta

journal homepage: www.elsevier.com/locate/clinchim

The role of External Quality Assessment Schemes in Monitoring and Improving the Standardization Process

Ferruccio Ceriotti *

[illegible]

Clinical Biochemistry 37 (2004) 13–19

Contents lists available at ScienceDirect

Clinical Biochemistry

journal homepage: www.elsevier.com/locate/clinbiochem

The role of external quality assessment in the verification of in vitro medical diagnostics in the traceability era

Federica Braga*, Sara Pasqualetti, Mauro Panteghini

Research Centre for Metrological Traceability in Laboratory Medicine (CIRME), University of Milan, Milan, Italy

Clinica Chimica Acta 432 (2014) 55–61

Contents lists available at ScienceDirect

Clinica Chimica Acta

journal homepage: www.elsevier.com/locate/clinchim

Verification of in vitro medical diagnostics (IVD) metrological traceability: Responsibilities and strategies

Federica Braga *, Mauro Panteghini

Centre for Metrological Traceability in Laboratory Medicine (CIRME), University of Milan, Milan, Italy

DE GRUYTER

Clin Chem Lab Med 2019; 57(7): 967–973

Mini Review

Federica Braga* and Mauro Panteghini

Commutability of reference and control materials: an essential factor for assuring the quality of measurements in Laboratory Medicine

https://doi.org/10.1515/cclm-2019-0354
Received February 6, 2019; accepted February 25, 2019; previously published online March 23, 2019

Abstract: Traceability to a common reference ensures

Introduction

Traceability to a common reference (ideally up to the International System of Units [SI]) ensures a high quality and

Original Article

Ann Clin Biochem 2000; **37**: 330–337

A model for harmonization of routine clinical chemistry results between clinical laboratories

Henk Baadenhuijsen[1], Ruud Scholten[2], Hans L Willems[1], Cas W Weykamp[3] and Rob T P Jansen[4]

From the [1]Department of Clinical Chemistry, Academic Hospital Nijmegen St Radboud, 116 SKZL, PO Box 9101, NL 6500 HB Nijmegen, [2]Virtual Central Laboratory, Zeist, [3]Department of Clinical Chemistry, Streekziekenhuis Queen Beatrix, Winterswijk, and the [4]Department of Clinical Chemistry, St Anna Hospital, Geldrop, the Netherlands [cooperation within the framework of the Dutch Foundation for Quality Assessment in Clinical Laboratories, SKZL]

Clinica Chimica Acta 432 (2014) 82–86

Contents lists available at ScienceDirect

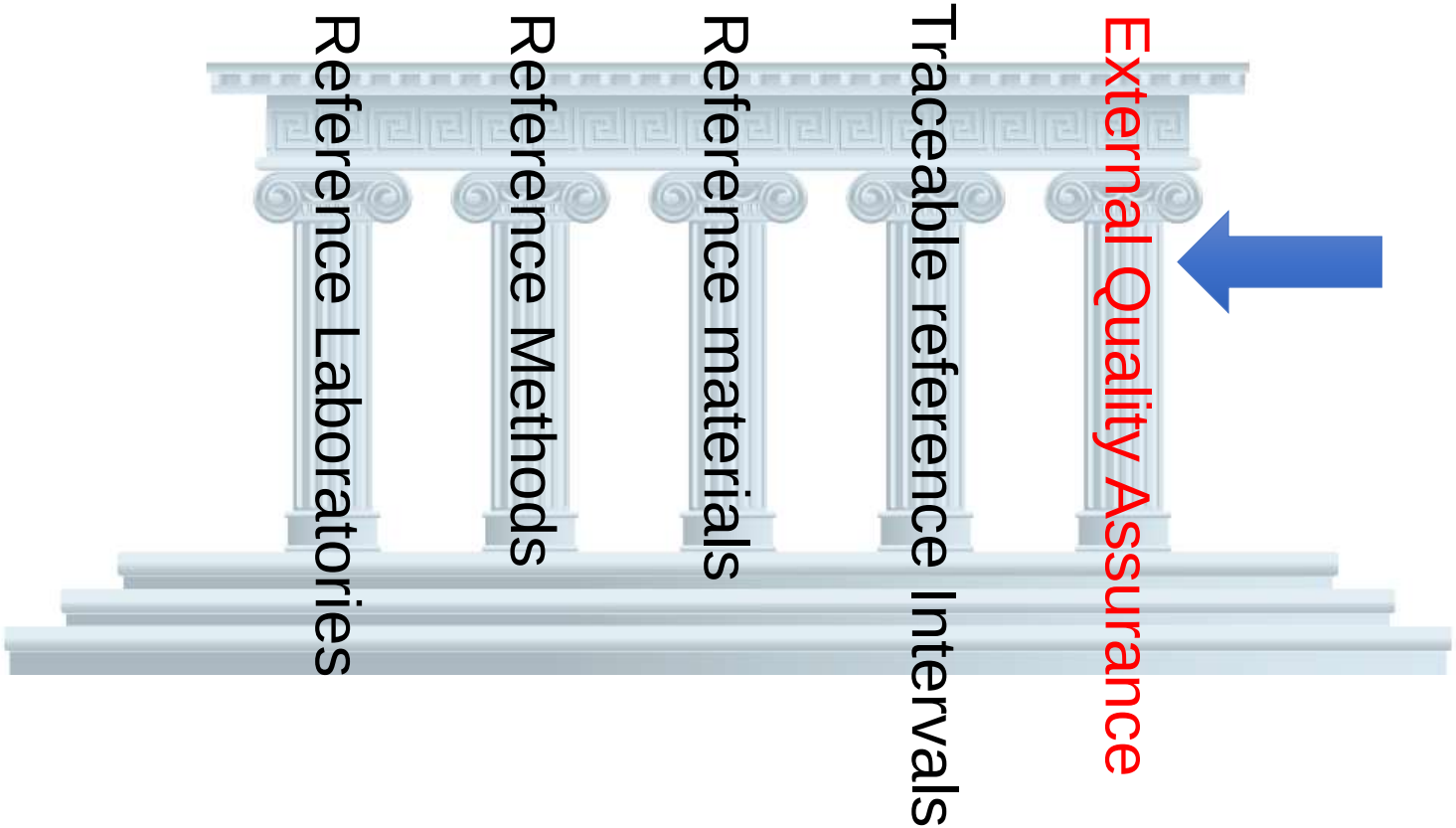
Clinica Chimica Acta

journal homepage: www.elsevier.com/locate/clinchim

External quality assurance programs as a tool for verifying standardization of measurement procedures: Pilot collaboration in Europe

C. Perich [a,b], C. Ricós [a,*], V. Alvarez [a,c], C. Biosca [a,c], B. Boned [a,c], F. Cava [a,c], M.V. Doménech [a,c], P. Fernández-Calle [a,b], P. Fernández-Fernández [a,c], J.V. García-Lario [a,c], J. Minchinela [a,b], M. Simón [a,c], R. Jansen [d,e]

Laboratory Method Standardisation



What are the challenges EQA providers face?

1. Material
2. Regulatory EQA schemes
3. Newer Areas of EQA
4. Sharing and Aggregating data
5. Education

What is the purpose of the EQA scheme?

- Regulatory
  - identify poorly performing laboratories
  - few challenges
  - wide APS
  - failure may involve punitive external inspection or loss of government funding
  - Consequently, laboratories may treat these EQA specimens differently to patient samples to ensure acceptable performance.


DE GRUYTER Clin Chem Lab Med 2020; 58(11): 1795–1797

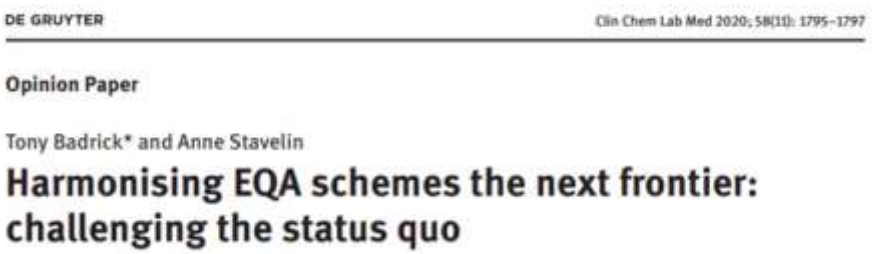
Opinion Paper

Tony Badrick* and Anne Stavelin

Harmonising EQA schemes the next frontier: challenging the status quo

What is the purpose of the EQA scheme?

- Aspirational
  - aim to improve the quality of laboratory testing
  - provide educational and sometimes research
  - APS is usually tighter and may be based on biological variation or “state of the art,” or a combination of the two
  - As a consequence of different APSs, a laboratory can have acceptable performance in one scheme and unacceptable in another for the same measurand.


DE GRUYTER Clin Chem Lab Med 2020; 58(11): 1795–1797

Opinion Paper

Tony Badrick* and Anne Stavelin

Harmonising EQA schemes the next frontier: challenging the status quo

DE GRUYTER

Clin Chem Lab Med 2015; 53(6): 919–924

Opinion Paper

Graham Ross Dallas Jones*

Analytical performance specifications for EQA schemes – need for harmonisation

DOI 10.1515/cclm-2014-1268
Received December 22, 2014; accepted March 18, 2015; previously published online April 17, 2015

Keywords: analytical performance criteria; External Quality Assurance; proficiency testing.

DE GRUYTER

Opinion Paper

Graham R.D. Jones*, Stephanie Albareda, Dagmar Kesseler, Finlay MacKenzie, Joy Mammen, Morten Pedersen, Anne Stavelin, Marc Thelen, Annette Thomas, Patrick J. Twomey, Emma Ventura and Mauro Panteghini, for the EFLM Task Finish Group – Analytical Performance Specifications for EQAS (TFG-APSEQA)

Analytical performance specifications for external quality assessment – definitions and descriptions

Frequency

Table 1: A comparison of the frequency of challenges in some EQA programs.

Provider	Program	Surveys per year	Samples per survey	Challenges per year	Frequency of analysis and reporting
BioRad	Chemistry and Immunoassay	24	1	24	2 weeks
RIQAS	Chemistry	26	1	26	2 weeks
UKNEQAS	Chemistry	24	3	72	2 weeks
UKNEQAS	HbA_{1c}	12	3	36	4 weeks
UKNEQAS	Specific Proteins	12	2	24	4 weeks
CAP	General Chemistry	3	5	15	4 months
CAP	Endocrinology	3	5	15	4 months
CAP	Lipids	2	3	6	6 months
CAP	*Calibration verification/Linearity sets	2	7	14	6 months
THISTLE programs (CEQAL)	Routine Chemistry	3	5	15	4 months
RCPAQAP	General Serum Chemistry	24	2	48	2 weeks
RCPAQAP	Condensed Chemistry Program	12	2	24	2 weeks

BioRad, BioRad Laboratories; RIQAS, Randox International Quality Assessment Scheme; UKNEQAS, United Kingdom National Quality Assessment Service; CAP, College of American Pathologists; CEQAL, Canadian External Quality Laboratory; RCPAQAP, Royal College of Pathologists of Australasia Quality Assurance Programs.

DE GRUYTER

Opinion Paper

Tony Badrick* and Peter Graham

Can a combination of average of normals and "real time" External Quality Assurance replace Internal Quality Control?

Frequency

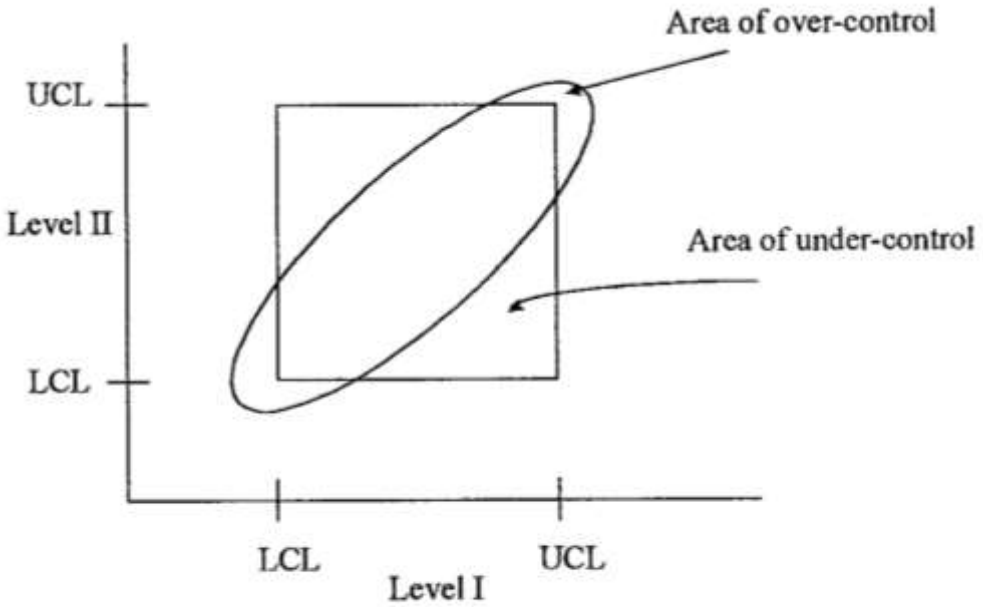


Fig. 1. Control region for two correlated control concentrations.

Clinical Chemistry 44:9
1959–1963 (1998)

Laboratory Management

Multivariate approach to quality control in clinical chemistry

JERRY DECHERT* and KENNETH E. CASE

What are the challenges EQA providers face?

1. Material
2. Regulatory EQA schemes
3. Newer Areas of EQA
4. Sharing and Aggregating data
5. Education

Opinion Paper

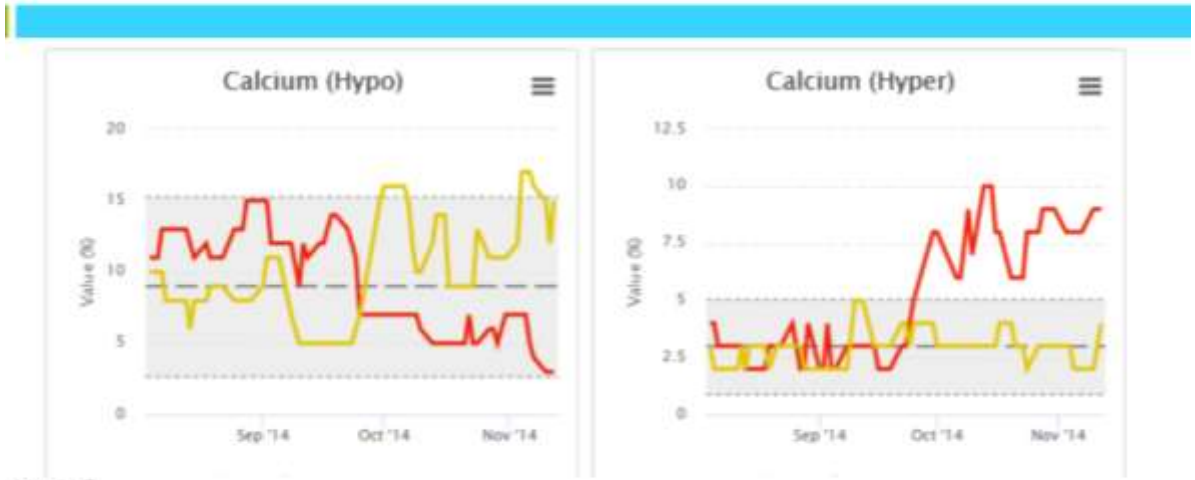
Tony Badrick* and Peter Graham

Can a combination of average of normals and "real time" External Quality Assurance replace Internal Quality Control?

https://doi.org/10.1515/cclm-2017-0115
Received February 8, 2017; accepted August 9, 2017

Abstract: Internal Quality Control and External Quality Assurance are separate but related processes that have developed independently in laboratory medicine over but often unrelated activities. IQC has a well-defined statistical basis for the rules to be used; however, the frequency of EQA challenges and determination of allowable limits varies widely across the available programs. Even the aims of different programs are different depending

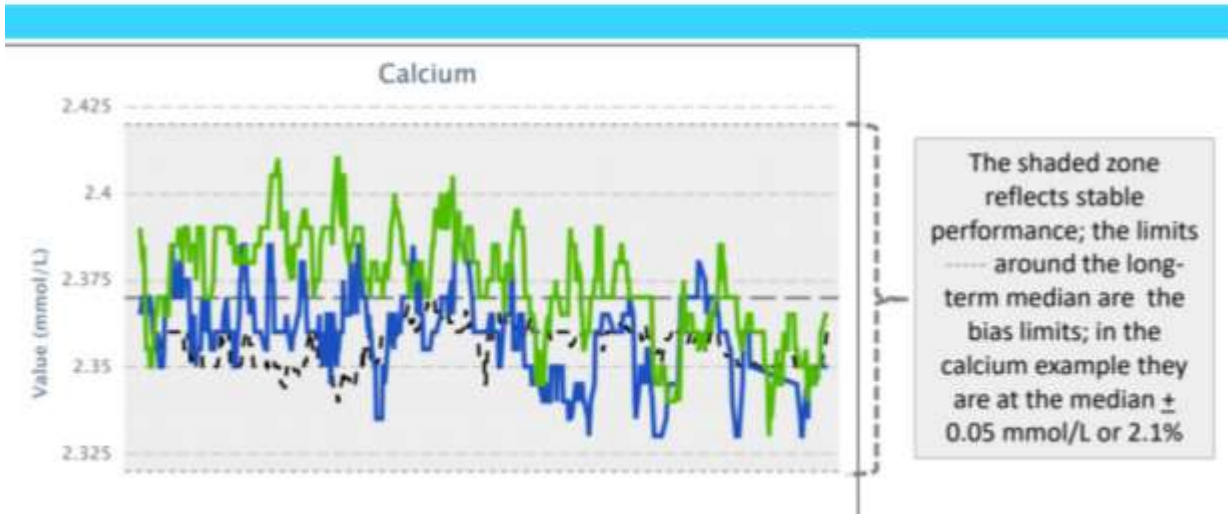
User interface – Flagger



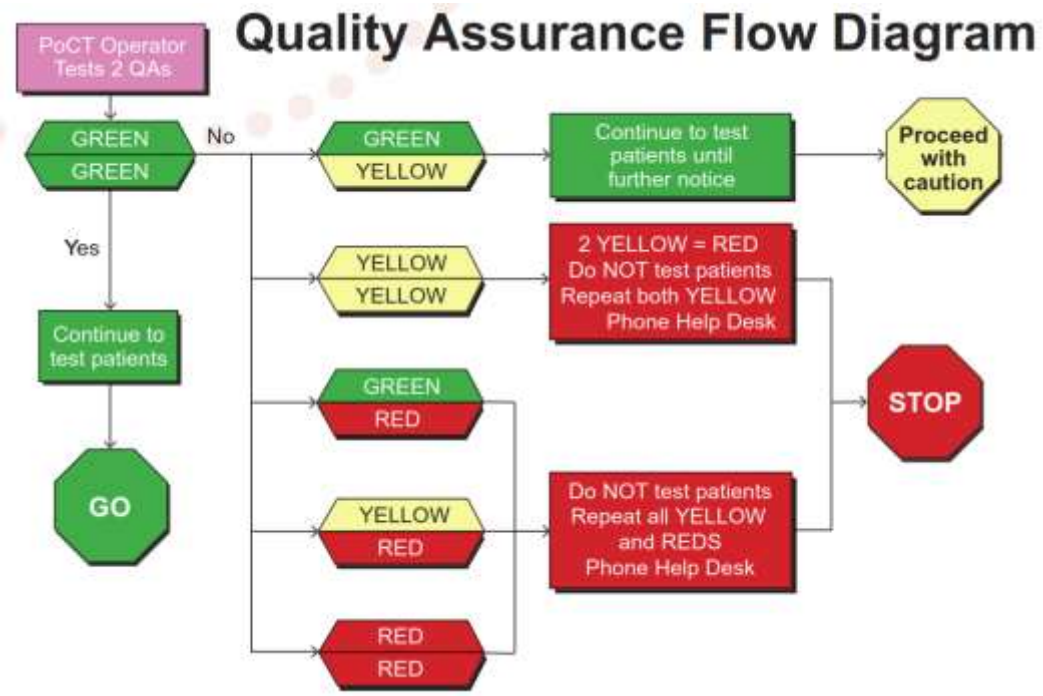
Legend:

Moving median of % hypo and hyper flagging rate from July 2014 to Nov '14 for two instruments in a laboratory.

User interface – Percentiler



Real time feedback provided



Human Mutation
Variation, Informatics, and Disease
OFFICIAL JOURNAL HGV HUMAN GENOME VARIATION SOCIETY
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View issue TOC
Volume 32, Issue 6
June 2011
Pages 696–697

Open Access

Letter to the Editors

The educational role of external quality assessment in genetic testing: a 7-year experience of the European Molecular Genetics Quality Network (EMQN) in Lynch syndrome†

JingHua Qiu, Pierre Hutter, Nils Rahner, Simon Patton, Sylviane Olschwang

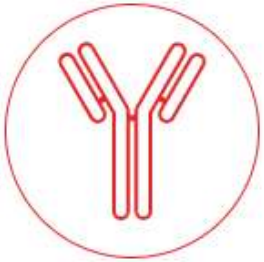
Anatomical Pathology

Biosecurity

Chemical Pathology

Cytopathology

Haematology



Immunology

KIMMS - Key Incident Management and Monitoring System

Microbiology

Molecular Genetics

Serology

Synovial Fluid

Transfusion

HER2 Brightfield ISH (BRISH) Gastric Diagnostic

Immunohistochemistry Breast Markers

Immunohistochemistry Breast Markers Audit

Immunohistochemistry General

Immunohistochemistry Lymphoma Markers

Immunohistochemistry Mismatch Repair (MMR) protein

Immunohistochemistry PD-L1

Mohs Diagnostic

Neuropathology Diagnostic

Neuropathology Immunohistochemistry and Technical

Oral and Maxillofacial Diagnostic

Paediatric Diagnostic

Renal Medical Diagnostic

ROS1 Translocation for non-small cell lung carcinoma (NSCLC)

Sarcoma Gene Testing

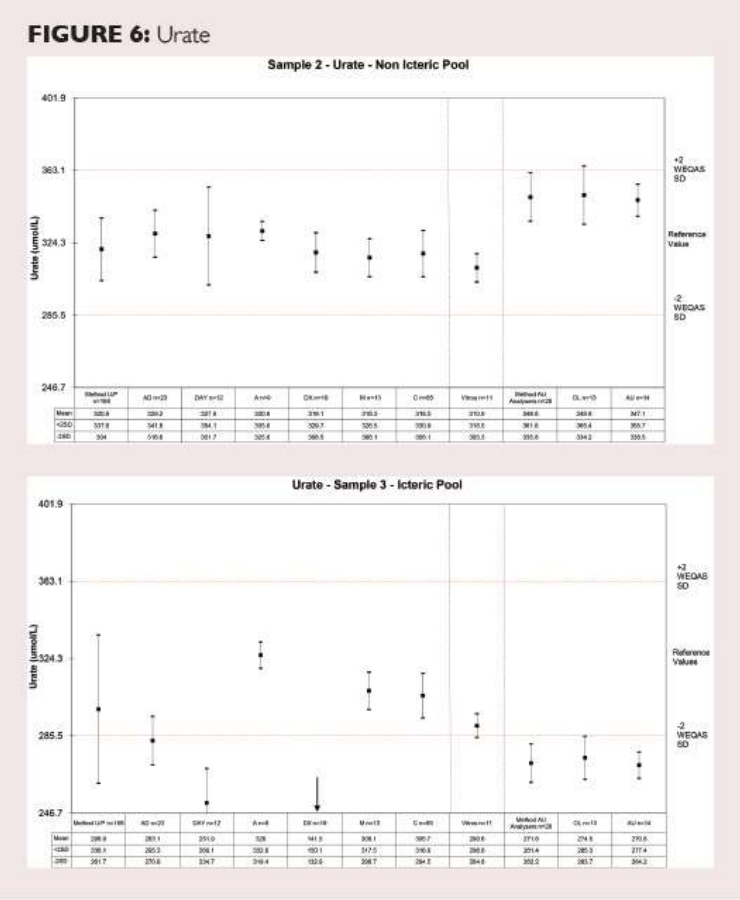
Technical Frozen Section

Technical General

Thoracic Diagnostic

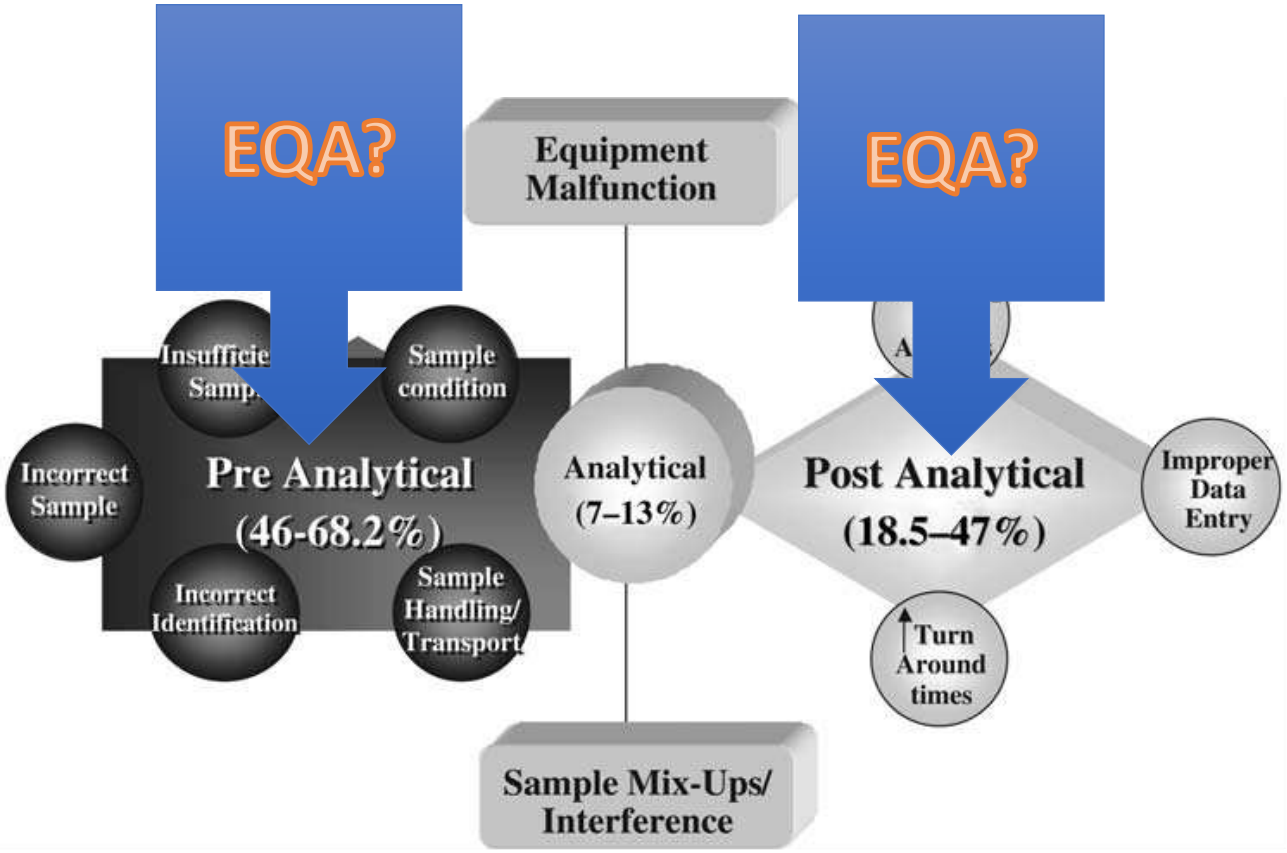
Urology Diagnostic

Pre-analytical errors due to abnormal serum indices may result in inadequate laboratory performance - WEQAS



Using conventional EQA scheme to highlight impact of pre-analytical error

Kalra clin biochem 37;1052-62: 2004



Pathology (June 2016) 48(4), pp. 357–362

CHEMICAL PATHOLOGY

Safe reading of chemical pathology reports: the RCPAQAP Report Assessment Survey

SABRINA KOETSIER[1], GRAHAM ROSS DALLAS JONES[1,2,3] AND TONY BADRICK[4]

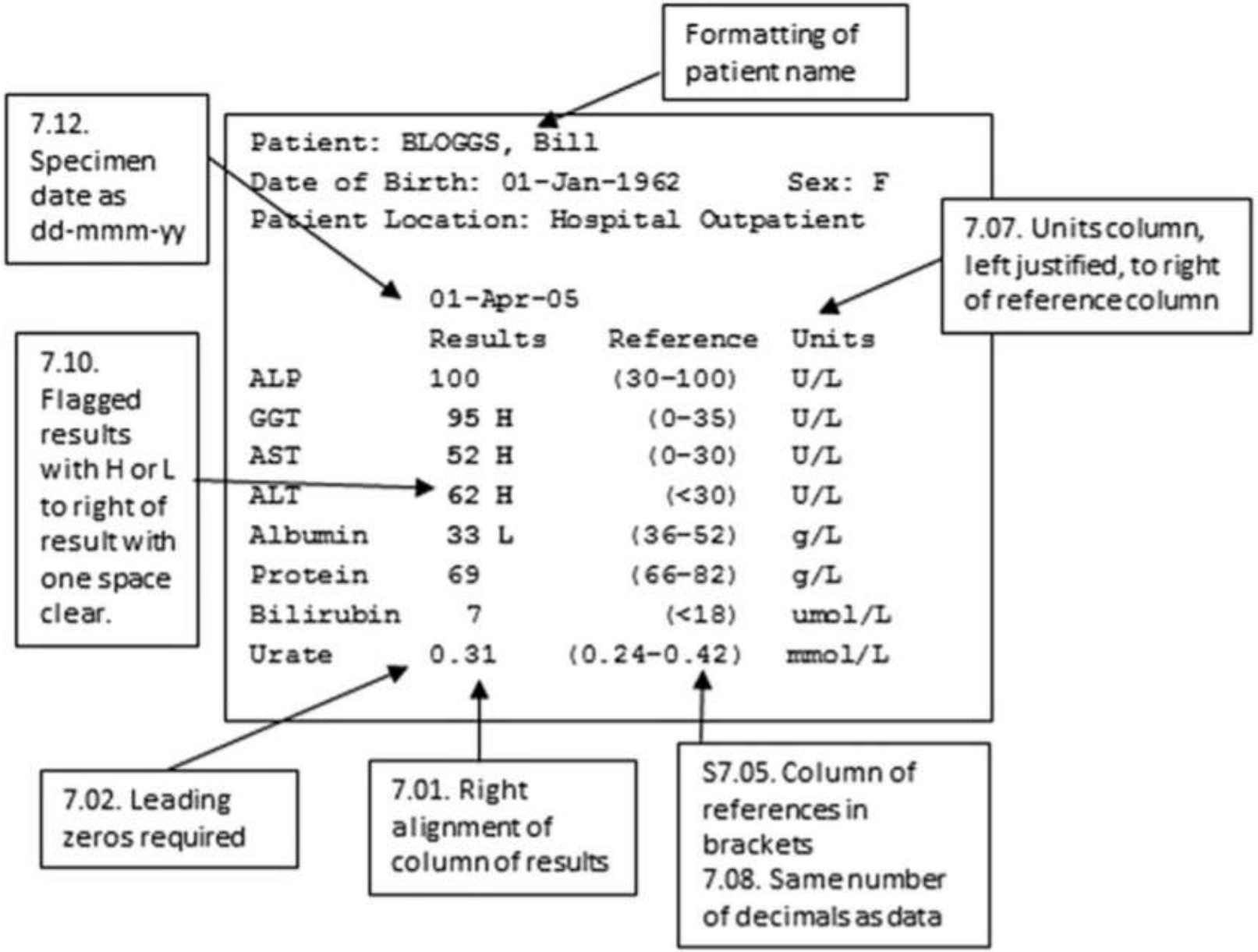
[1]*RCPAQAP Chemical Pathology, Adelaide, SA,* [2]*St Vincent's Hospital, Darlinghurst,* [3]*University of NSW, Kensington, and* [4]*RCPAQAP, St Leonards, NSW, Australia*

Summary

Pathology reports are a vital component of the request-test-report cycle communicating pathology results to doctors to support clinical decision making. This should be done in a comprehensive, safe and time-efficient manner. As doctors may receive reports from different laboratories these goals can be achieved more readily if reports are formatted in the same way.

This study evaluates the formatting of paper reports produced by Australian laboratories for numerical biochemistry results. As part of the RCPAQAP Liquid Serum Chemistry program in 2015, laboratories were invited to supply a routine paper report displaying the results. A total of 37 reports were received for analysis. These reports were assessed for variation in a range of components and, where possible, against relevant Australian standards and guidelines. In summary, there was a wide variation in most of the report components assessed including test names, uncertainty reported in this study potentially affects 23 million patients per year and raises significant concerns.[1]

Additionally if a report is difficult to read, there can be valuable time lost in trying to correctly identify the key elements of the results. As noted by Stephen Ruby in 2000: 'The elements found to influence the understanding of a report's content include spacing, highlighting, formatting and font selection. These items, in and of themselves do not contribute to the content of the report; however they do appear to contribute substantially to the comprehension of that report.'[2] In the modern era doctors commonly receive pathology reports from a range of different laboratories. Examples include tests requested by a specialist, results from a hospital, results obtained while travelling or results from a different laboratory attended by the patient for convenience or other reasons. Against this background it can be seen that uniformity of reporting formats amongst laboratories can be beneficial in making the review of pathology reports easier and safer, irrespective of the testing laboratory.[3]


Formatting of patient name
7.12. Specimen date as dd-mmm-yy
Patient: BLOGGS, Bill
Date of Birth: 01-Jan-1962 Sex: F
Patient Location: Hospital Outpatient
01-Apr-05
Results Reference Units
ALP 100 (30-100) U/L
GGT 95 H (0-35) U/L
AST 52 H (0-30) U/L
ALT 62 H (<30) U/L
Albumin 33 L (36-52) g/L
Protein 69 (66-82) g/L
Bilirubin 7 (<18) umol/L
Urate 0.31 (0.24-0.42) mmol/L
7.07. Units column, left justified, to right of reference column
7.10. Flagged results with H or L to right of result with one space clear.
7.02. Leading zeros required
7.01. Right alignment of column of results
S7.05. Column of references in brackets
7.08. Same number of decimals as data

EQA for Referring Doctors

Clinical Chemistry 51:7
1145–1153 (2005)

Evidence-Based
Laboratory Medicine
and Test Utilization

Postanalytical External Quality Assessment of Blood Glucose and Hemoglobin A_{1c}: An International Survey

Svein Skeie,[1*] Carmen Perich,[2] Carmen Ricos,[2] Agnes Araczki,[3] Andrea R. Horvath,[3] Wytze P. Oosterhuis,[4] Tanya Bubner,[5] Gunnar Nordin,[6] Rhena Delport,[7] Geir Thue,[1] and Sverre Sandberg[1]

Background: Diabetes mellitus (DM) is diagnosed and monitored worldwide by blood glucose (BG) and glycohemoglobin A_{1c} (HbA_{1c}) testing, respectively. Methods for quality assessment of clinician interpretations of changes in these laboratory results have been developed. This study uses survey responses from general practitioners (GPs) in different countries to investigate possible differences in interpretation of results, as well as the feasibility of performing international postanalytical external quality assessment surveys (P-EQAS).

Methods: GPs recruited from 7 countries received questionnaires requesting interpretation of changes in a potentially diagnostic capillary BG result and an HbA_{1c} value obtained during monitoring of a patient with type 2 DM. GPs were asked to estimate clinically significant differences between 2 consecutive laboratory results [critical difference (CD)/reference change value] for both BG and HbA_{1c}. The CDs reported by GPs were used to calculate the analytical variation (CV_A), which was taken as the quality specification for analytical imprecision. Participants received national benchmarking feedback reports after the survey.

Results: The study included responses from 2538 GPs. CDs in BG results showed the same pattern and were comparable among countries. Calculated median CV_A values would be possible to attain at 80% confidence but not at the conventional 95% confidence. For HbA_{1c}, the same pattern was shown across countries, but with lower changes considered true when HbA_{1c} increased than when it decreased. Despite the consistent pattern, variations among GPs were considerable in all countries.

Conclusions: Assessments of CDs for BG and HbA_{1c} were similar internationally, and quality specifications for these analytes based on clinicians' opinions are therefore interchangeable among countries. International P-EQAS may contribute to a more rational use of laboratory services and clinical guidelines.

Because of the rapid worldwide increase in diabetes

Clinical Chemistry 52:10
1871–1878 (2006)

Evidence-Based
Laboratory Medicine
and Test Utilization

Postanalytical External Quality Assessment of Warfarin Monitoring in Primary Healthcare

Ann-Helen Kristoffersen,[1*] Geir Thue,[2] and Sverre Sandberg[1,2]

Background: An increasing number of patients are treated with warfarin worldwide, and many are monitored in general practice, often with office instruments. Bleeding or thromboembolic episodes may be consequences of inadequate treatment. We have therefore examined some important aspects of general practitioners' (GPs') knowledge of warfarin treatment.

Methods: A questionnaire including 2 case histories with familiar indications for warfarin treatment (mechanical heart valve prosthesis and pulmonary embolism) was circulated to 3781 GPs in Norway as a postanalytical quality assessment.

Results: A total of 1547 GPs (41%) responded. There were substantial variations among GPs concerning the frequency of international normalized ratio (INR) monitoring, stated therapeutic ranges for arterial (but not venous) indications for anticoagulation therapy, and handling of a moderately high INR result of 5.9. Most GPs estimated an unrealistically high risk of serious bleeding in the latter situation (median, 15%; 10th and 90th percentiles, 4% and 50%, respectively). The critical difference necessary to change the warfarin dose was highly dependent on perceived therapeutic intervals, and about half of the GPs suggested a critical difference of 0.8 INR, which is attainable with office instruments. Sex and age of the GPs, practice size, and availability of an INR instrument in the office laboratory did not

commendations for treatment and monitoring of these patients are still needed.

The effectiveness of oral anticoagulant treatment with vitamin K antagonists (coumarin derivatives) has been demonstrated for several indications in the last decades, and the use of this treatment is increasing. The most important indications are atrial fibrillation, venous thromboembolism, and prevention of systemic embolism in patients with prosthetic heart valves. Several studies have also shown a marked decrease in mortality after myocardial infarction (*1*).

The drawbacks of vitamin K antagonist treatment are that regular laboratory control of prothrombin time international normalized ratio (INR)[9] and individualized dose adjustment within narrow therapeutic intervals are necessary to avoid bleeding or thromboembolic complications (*2*). Every year, 1% of users experience a major bleeding episode, and fatal bleeding occurs in 0.25%–0.5% annually (*3*). The risk of thromboembolism increases with the use of low-intensity therapy (INR 1.5–1.9) compared with conventional-intensity therapy (INR 2.0–3.0), from 0.7 per 100 person-years to 1.9 per 100 person-years (*4*). Thus, good therapeutic control and time spent within the therapeutic interval have been associated with a decrease in bleeding and thromboembolic complications (*3*, *4*).

Clinical Audit


Clinical Biochemistry

journal homepage: www.elsevier.com/locate/clinbiochem

Diagnostic laboratories in Asia Pacific region: Investigation on quality characteristics and time of reporting

Tony C. Badrick, Anton Gutscher, Nakako Sakamoto, Daniel Chin


Original Article

A current analysis of quality indicators in Chin laboratories

Mohamed Saleem, Wesley Wong, Xian-Zhang Huang, Tony Badrick


Diagnostic Laboratories in India: Investigating Quality Characteristics, Productivity and Time of Reporting


Turnaround times and modes of reporting critical results in Asian laboratories


OPEN ACCESS – ORIGINAL ARTICLE

Philippines Diagnostic Pathology Laboratory Benchmarking

Tony Badrick, Jasica Habiljanic, Sam Yew Mah, Elizabeth Arcellana-Mucul

ABSTRACT

Introduction. To ensure continuous quality improvement, laboratories need to obtain data about best practice from peers. Data about analytical EQA is available but far less is available about other important aspects of laboratory performance. There is a Roche Diagnostics Survey of laboratories which provides benchmarking in key areas of laboratory performance.

Methodology. The Roche Diagnostics Survey included 1058 laboratories from 14 countries in the Asia Pacific Region with both developing and developed nations. The data were collected in 2017 but the survey has been collecting data each second year since 2011. Data was collected in the areas of quality, speed and cost.

Results. The results for the Philippines was compared with other countries in the Asia Pacific Region. Broadly it was found that 42% of all laboratories in the Region were accredited to ISO 15189 or ISO 9001 and that 50% of laboratories were in an External Quality Assurance (EQA) program. Compared to other countries in the survey, the Philippines laboratories had fewer sites with ISO 15189 and with Lean Six Sigma improvement deployment. There are six laboratories in the Philippines that are accredited to ISO 15189. There was a greater emphasis on customer satisfaction related Key Performance Indicators (KPIs) such as turnaround time monitoring, cost reduction and employee productivity.

Conclusions. Benchmarking can highlight the differences in the apparent quality of laboratory services compared to their peers and may lead to improvement. The benchmarking comparison has identified opportunities for Philippine laboratories to improve including obtaining ISO 15189 accreditation, implementing laboratory information systems and concentrating on Lean practices to improve productivity. The Roche scheme provides an ongoing (growing) large sample of benchmarks that can be used by participants to improve their performance and the performance of individual countries.

Key words: benchmarking, quality, cost of service, customer satisfaction, turnaround time

INTRODUCTION


Clinical audit in the laboratory

R T Erasmus, A E Zemlin

ABSTRACT

What are the challenges EQA providers face?

1. Material
2. Regulatory EQA schemes
3. Newer Areas of EQA
4. Sharing and Aggregating data
5. Education

Special issue: External Quality Assessment in Laboratory Medicine

Review

The role of EQA in harmonization in laboratory medicine – a global effort

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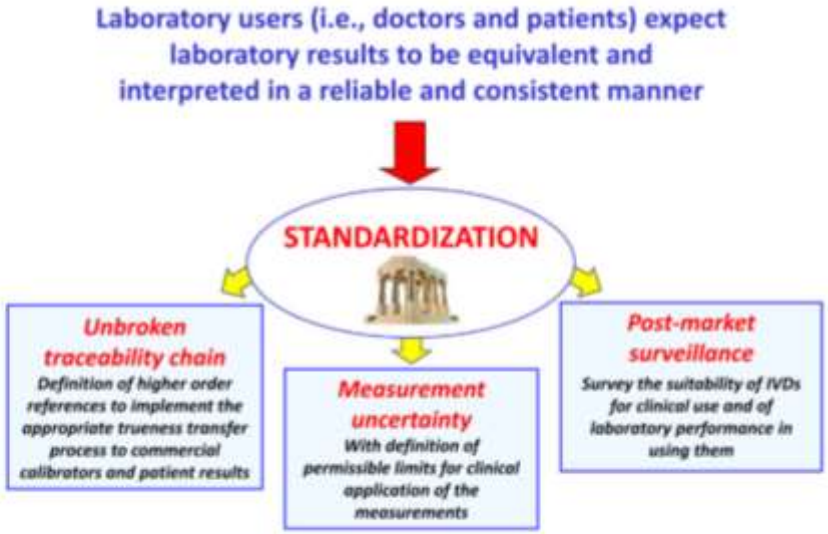

Fig. 2. Scheme describing the main components needed to produce standardized laboratory results. IVDs, in vitro diagnostics.

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Monitoring laboratory data across manufacturers and laboratories—A prerequisite to make "Big Data" work

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Moving median
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Drifts

ABSTRACT

Background: "The Percentiler" project provides quasi real-time access to patient medians across laboratories and manufacturers. This data can serve as "clearinghouse" for electronic health record applications, e.g., use of laboratory data for global health-care research.
Methods: Participants send their daily outpatient medians to the Percentiler application. After 6 to 8 weeks, the laboratory receives its login information, which gives access to the user interface. Data is assessed by peer group, i.e., 10 or more laboratories using the same test system. Participation is free of charge.
Results: Participation is global with, to date, >120 laboratories and >250 instruments. Up to now, several reports have been produced that address i) the general features of the project, ii) peer group observations; iii) synergisms between "The Percentiler" and dedicated external quality assessment surveys. Reasons for long-term instability and bias (calibration- or lot-effects) have been observed for the individual laboratory and manufacturers.
Conclusions: "The Percentiler" project has the potential to build a continuous, global evidence base on in vitro diagnostic test comparability and stability. As such, it may be beneficial for all stakeholders and, in particular, the patient. The medical laboratory is empowered for contributing to the development, implementation, and management of global health-care policies.

What are the challenges EQA providers face?

1. Material
2. Regulatory EQA schemes
3. Newer Areas of EQA
4. Sharing and Aggregating data
5. Education

Educating our participants

- Do they understand what EQA is for?
- See it as an exam to pass
- Perhaps they game the system?
- They are only interested in their results, not the boarder aspects of harmonisation and traceability
- Who is responsible to educate them?

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Commutability and traceability in EQA programs

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Reference material
Patient sample commutability
Traceability

ABSTRACT

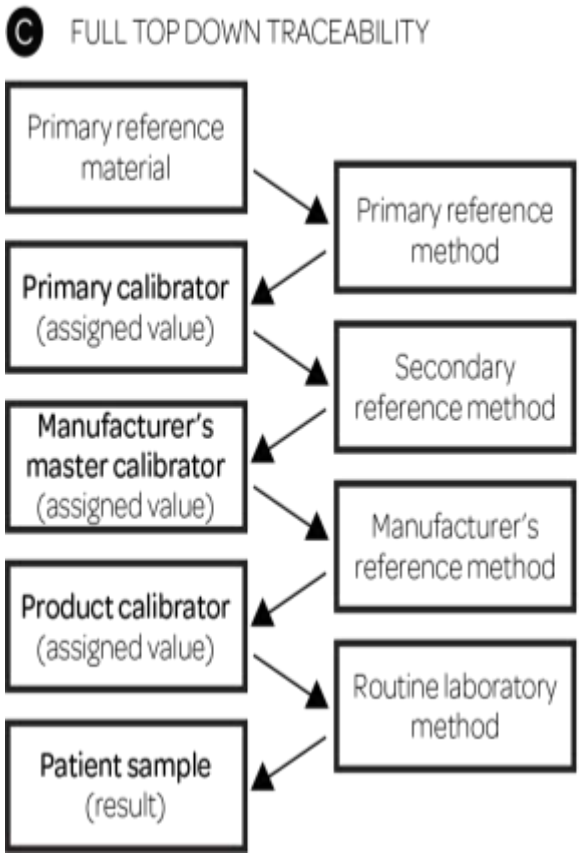
Objectives: The concept of commutability of samples has focused laboratories on the importance of traceability. However, the critical role of External Quality Assurance (EQA) in achieving the primary role of traceability (i.e. facilitating comparable patient results in different laboratories) has largely been lost. The aim of this paper is to review the role of EQA in achieving traceable/commutable results.

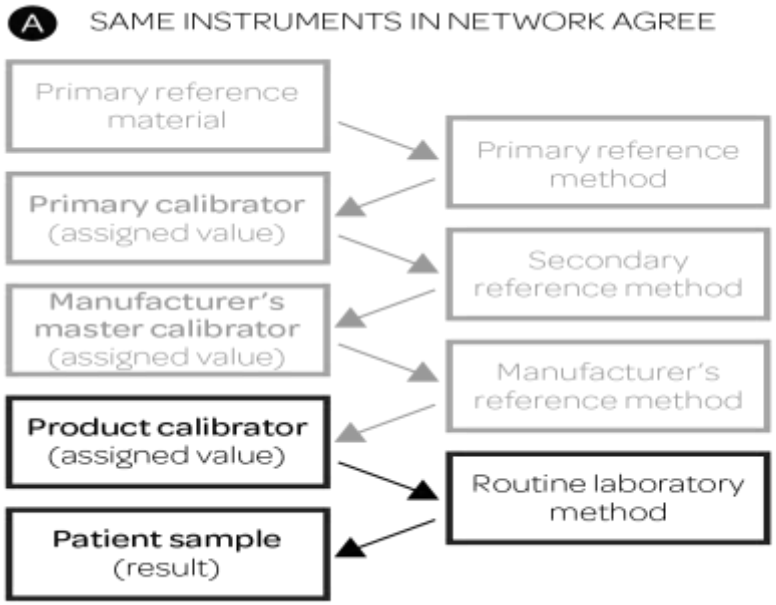
Design and methods: The role of commutability and traceability in EQA and Internal Quality Control (IQC) are discussed. Examples of commutable EQA samples are given to highlight the problem of assuming EQA material does not behave like patient samples.

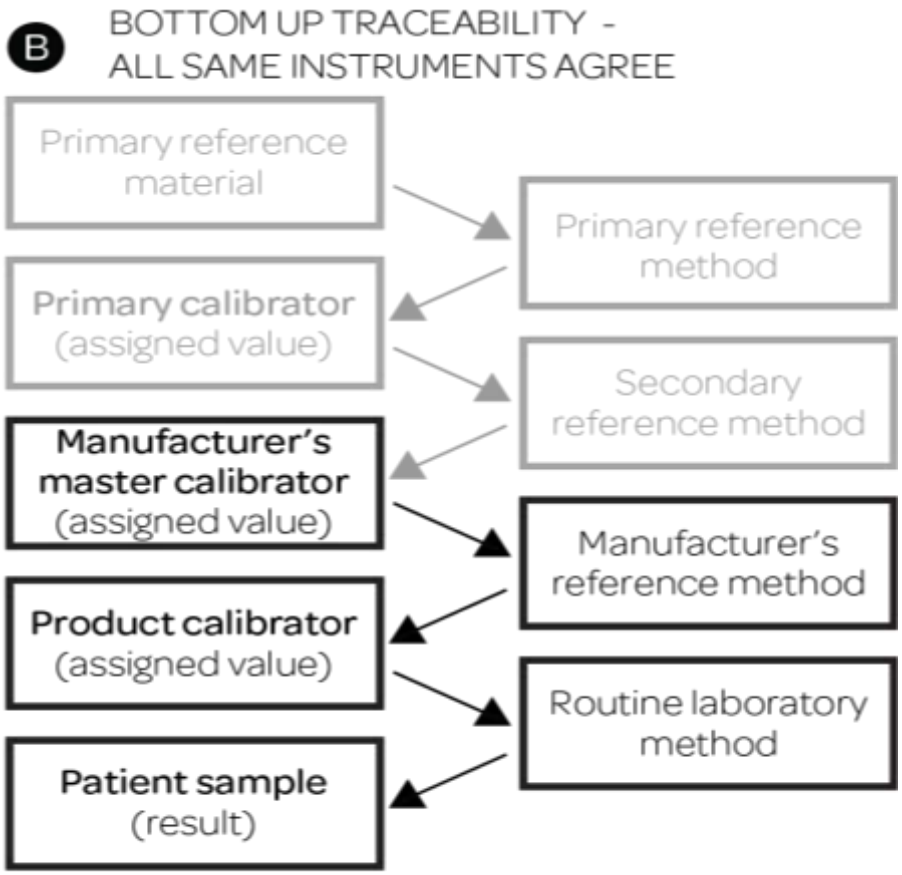
Results: We provide the conventional traceability chain (top down) and the role of EQA in a "bottom up" model using conventional EQA samples.

Conclusions: The quest for commutable samples has compromised the value of EQA without an understanding that some EQA materials are commutable for some measurands.

EQA plays a key role in performance improvement, but laboratories need to understand the importance of using a range of values appropriate to the assay to identify areas of quality need. Traceability and EQA using conventional samples are not mutually exclusive concepts.


C
FULL TOP DOWN TRACEABILITY
Primary reference material
Primary reference method
Primary calibrator (assigned value)
Secondary reference method
Manufacturer's master calibrator (assigned value)
Manufacturer's reference method
Product calibrator (assigned value)
Routine laboratory method
Patient sample (result)


A
SAME INSTRUMENTS IN NETWORK AGREE
Primary reference material
Primary calibrator (assigned value)
Manufacturer's master calibrator (assigned value)
Product calibrator (assigned value)
Patient sample (result)
Primary reference method
Secondary reference method
Manufacturer's reference method
Routine laboratory method


B
BOTTOM UP TRACEABILITY -
ALL SAME INSTRUMENTS AGREE
Primary reference material
Primary calibrator (assigned value)
Manufacturer's master calibrator (assigned value)
Product calibrator (assigned value)
Patient sample (result)
Primary reference method
Secondary reference method
Manufacturer's reference method
Routine laboratory method

What are the challenges EQA providers face?

1. Material –
   a) significant, perhaps not essential to always have commutable and value assignment
   b) When is it important?

2. Regulatory EQA schemes
   a) Need to lobby as a profession

3. Newer Areas of EQA
   a) Constant challenges
   b) Pre and post analytical are major sources of error

What are the challenges EQA providers face?

4. Sharing and Aggregating data
   a) Achievable
   b) Resources

5. Education
   a) Critical to future

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